Docket No. MCP-291

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	KULKARNI et al.
Serial No.	:	
Filed	:	
Title	:	PREBLEND OF MICROCRYSTALLINE CELLULOSE AND LACTASE FOR MAKING TABLETS
Art Unit	:	
Examiner	:	

Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Prior to the examination of the captioned application, please amend the application as follows:

In the Title:

Please cancel the title entered in Paper No. 14 of US Patent Application Ser. No. 09/526,627 and insert the following title - -

STABLE LACTASE TABLETS AND METHODS OF PRODUCTION - -

In the Abstract:

Please cancel the abstract entered in Paper No. 14 of US Patent Application Ser. No. 09/526,627 and insert the following abstract

A tablet and a composition having from about 3000 to about 9000 FCC lactase units and from about 25 to about 70 weight percent microcrystalline cellulose is disclosed. Additionally, also disclosed is a process for making a tablet by following steps in order mixing lactase and microcrystalline cellulose to form a preblend; adding to the preblend a member selected from the group consisting of dextrose, mannitol, a lubricant, cornstarch, calcium phosphate, sodium citrate, calcium sulfate, calcium stearate, stearic acid, gylceryl

monostearate, glyceryl distearate, sorbitol, gelatin, a gum, and mixtures thereof to form a mixture; and compressing the mixture to form a tablet.

In the Specification:

Please amend the statement at page 1 before the first line, entered in Paper No. 14 of US Patent Application Ser. No. 09/526,627 as follows:

This application is a division of US Patent Application Ser. No. 09/526,627, filed August 16, 2000, currently pending, which was a division of US Patent Application 08/496,824, filed June 29, 1995, now US Patent No. 6,057,139.

49. In the Claims:

Please cancel claims 1-17.

Please add the following claims:

18. (New) A tablet comprising
    (a) from about 3000 to about 9000 FCC lactase units and
    (b) from about 25 to about 70 weight percent microcrystalline cellulose.

19. (New) A tablet according to claim 18 further comprising a member selected from the group consisting of dextrose, mannitol, a lubricant, cornstarch, calcium phosphate, sodium citrate, calcium sulfate, calcium stearate, stearic acid, gylceryl monostearate, glyceryl distearate, sorbitol, gelatin, a gum, and mixtures thereof.

20. (New) A tablet according to claim 19 comprising dextrose, sodium citrate, and a lubricant.

21. (New) A tablet according to claim 19 comprising manitol, dextrose, sodium citrate, and a gum.

22. (New) A tablet according to claim 21 wherein the gum is selected from the group consisting of carboxymethyl cellulose, methyl cellulose, alginate, dextran, acacia gum, karaya gum, locust bean gum, and tragacanth.

23. (New) A tablet according to claim 22 wherein the gum is carboxymethyl cellulose.

24. (New) A tablet according to claim 19 wherein the lubricant is selected from the group consisting of magnesium stearate, talc, polyethylene glycol, silica, hardened vegetable oils, and mixtures thereof.

25. (New) A tablet according to claim 20 wherein the lubricant is selected from the group consisting of magnesium stearate, talc, polyethylene glycol, silica, hardened vegetable oils, and mixtures thereof.

26. (New) A tablet according to claim 24 wherein the lubricant is magnesium stearate.

27. (New) A tablet according to claim 25 wherein the lubricant is magnesium stearate.

28. (New) A tablet according to claim 19 wherein the lubricant is present in an amount of from about 0.25 to about 6 % by weight.

29. (New) A tablet according to claim 20 wherein the lubricant is present in an amount of from about 0.25 to about 6 % by weight.

30. (New) A tablet comprising
    (a) about 3000 FCC lactase units;
    (b) from about 25 to about 70 weight percent microcrystalline cellulose;
    (c) from about 25 to about 70 weight percent mannitol;
    (d) from about 0.25 to about 6 weight percent magnesium stearate;
    (a) carboxymethyl cellulose;
    (b) dextrose; and
    (c) sodium citrate.

31. (New) A tablet comprising
    (a) about 9000 FCC lactase units;
    (b) from about 25 to about 70 weight percent microcrystalline cellulose;
    (c) from about 25 to about 70 weight percent mannitol;
    (d) from about 0.25 to about 6 weight percent magnesium stearate;
    (e) carboxymethyl cellulose;
    (f) dextrose; and
    (g) sodium citrate.

32. (New) A tablet comprising
    (a) about 9000 FCC lactase units;
    (b) from about 25 to about 70 weight percent microcrystalline cellulose;
    (c) from about 0.25 to about 6 weight percent magnesium stearate;
    (d) dextrose; and
    (e) sodium citrate.

33. (New) A composition comprising
    (a) from about 3000 to about 9000 FCC lactase units and
    (b) from bout 25 to about 70 weight percent microcrystalline cellulose.

34. (New) A composition according to claim 33 further comprising a member selected from the group consisting of dextrose, mannitol, a lubricant, cornstarch, calcium phosphate, sodium citrate, calcium sulfate, calcium stearate, stearic acid, gylceryl monostearate, glyceryl distearate, sorbitol, gelatin, a gum, and mixtures thereof.

35. (New) A composition according to claim 34 comprising dextrose, sodium citrate, and a lubricant.

36. (New) A composition according to claim 34 comprising manitol, dextrose, sodium citrate, and a gum.

37. (New) A composition according to claim 36 wherein the gum is selected from the group consisting of carboxymethyl cellulose, methyl cellulose, alginate, dextran, acacia gum, karaya gum, locust bean gum, and tragacanth.

38. (New) A composition according to claim 37 wherein the gum is carboxymethyl cellulose.

39. (New) A composition according to claim 34 wherein the lubricant is selected from the group consisting of magnesium stearate, talc, polyethylene glycol, silica, hardened vegetable oils, and mixtures thereof.

40. (New) A composition according to claim 35 wherein the lubricant is selected from the group consisting of magnesium stearate, talc, polyethylene glycol, silica, hardened vegetable oils, and mixtures thereof.

41. (New) A composition according to claim 40 wherein the lubricant is magnesium stearate.

42. (New) A composition according to claim 35 wherein the lubricant is magnesium stearate.

43. (New) A composition according to claim 34 wherein the lubricant is present in an amount of from about 0.25 to about 5 % by weight.

44. (New) A composition according to claim 35 wherein the lubricant is present in an amount of from about 0.25 to about 5 % by weight.

45. (New) A composition comprising
    (a) about 3000 FCC lactase units;
    (b) from about 25 to about 70 weight percent microcrystalline cellulose;
    (c) from about 25 to about 70 weight percent mannitol;
    (d) from about 0.25 to about 6 weight percent magnesium stearate;
    (e) carboxymethyl cellulose;
    (f) dextrose; and
    (g) sodium citrate.

46. (New) A composition comprising
    (a) about 9000 FCC lactase units;
    (b) from about 25 to about 70 weight percent microcrystalline cellulose;
    (c) from about 25 to about 70 weight percent mannitol;
    (d) from about 0.25 to about 6 weight percent magnesium stearate;
    (e) carboxymethyl cellulose;
    (f) dextrose; and
    (g) sodium citrate.

47. (New) A composition comprising
    (a) about 9000 FCC lactase units;
    (b) from about 25 to about 70 weight percent microcrystalline cellulose;
    (c) from about 0.25 to about 6 weight percent magnesium stearate;
    (d) dextrose; and
    (e) sodium citrate.

48. (New) A process for making a tablet comprising the following steps in order
    (a) mixing lactase and microcrystalline cellulose to form a preblend;
    (b) adding to the preblend a member selected from the group consisting of dextrose, mannitol, a lubricant, cornstarch, calcium phosphate, sodium citrate, calcium sulfate, calcium stearate, stearic acid, gylceryl monostearate, glyceryl distearate, sorbitol, gelatin, a gum, and mixtures thereof to form a mixture; and
    (c) compressing the mixture to form a tablet.

49. (New) A process according to claim 48 wherein dextrose, sodium citrate, and a lubricant are added to the preblend.

50. (New) A process according to claim 48 wherein manitol, dextrose, sodium citrate, and a gum are added to the preblend.

51. (New) A process according to claim 33 wherein the gum is selected from the group consisting of carboxymethyl cellulose, methyl cellulose, alginate, dextran, acacia gum, karaya gum, locust bean gum, and tragacanth.

52. (New) A process according to claim 34 wherein the gum is carboxymethyl cellulose.

53. (New) A process according to claim 31 wherein the lubricant is selected from the group consisting of magnesium stearate, talc, polyethylene glycol, silica, hardened vegetable oils, and mixtures thereof.

54. (New) A process according to claim 32 wherein the lubricant is selected from the group consisting of magnesium stearate, talc, polyethylene glycol, silica, hardened vegetable oils, and mixtures thereof.

55. (New) A process according to claim 36 wherein the lubricant is magnesium stearate.

56. (New) A process according to claim 37 wherein the lubricant is magnesium stearate.

57. (New) A process according to claim 36 wherein the lubricant is present in an amount of from about 0.25 to about 6 % by weight.

58. (New) A process according to claim 37 wherein the lubricant is present in an amount of from about 0.25 to about 6 % by weight.

59. (New) A process for making a tablet comprising

(a) mixing an amount lactase having a potency of between about 14,000 and about 100,000 FCC units and about 25 to about 85 weight percent microcrystalline cellulose to form a preblend;

(b) adding from about 25 to about 70 weight percent of the tablet of mannitol; from about 0.25 to about 5 weight percent of the tablet of magnesium stearate; carboxymethyl cellulose; dextrose; and sodium citrate to form a mixture;

(c) and compressing the mixture to form the tablet.

60. (New) A process for making a tablet comprising

(a) mixing an amount lactase having a potency of between about 14,000 and about 100,000 FCC units and about 25 to about 85 weight percent microcrystalline cellulose to form a preblend;

(b) adding from about 0.25 to about 5 weight percent of the tablet of magnesium stearate; dextrose; and sodium citrate to form a mixture; and

(c) compressing the mixture to form the tablet.

REMARKS/ARGUMENTS

This new application is being filed before the payment of the Issue Fee in US Patent Application Ser. No. 09/526,627 (Issue Batch K11).

Claims 7-17 have been canceled without prejudice.

Support for independent claims 18 and 33 can be found throughout the specification at, for example, page 3, lines 26-28 and page 4, line 33 – page 5, line 5.

Support for claims 19-27 and 34-42 can be found throughout the specification at, for example, page 3, lines 14-16, page 4, lines 1-21, Example 1 and Example 2.

Support for claims 28, 29, 43 and 44 can be found throughout the specification at, for example, page 2, lines 27-29 and page 4, lines 21-23.

Support for claims 30-32 and 45-47 can be found throughout the specification at, for example, page 5, lines 3-5, page 3, lines 26-28, page 4, lines 16-18, page 4, lines 21-23, page 4, lines 6-13, and page 2, lines 27-29.

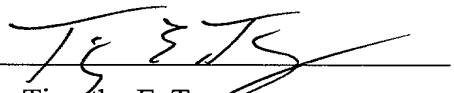
Support for claims 48-56 can be found throughout the specification at, for example, page 1, lines 17-29, page 3, lines 29-31, page 4, lines 1 – 23 and Example 2.

Support for claims 59 and 60 can be found throughout the specification at, for example, page 3, lines 6-12, page 3, lines 26-27, page 3, lines 29-34, and page 4, lines 1-23.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned "Version with markings to show changes made".

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: 

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Dated: November 2, 2001

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Title:

The title entered in Paper No. 14 of US Patent Application Ser. No. 09/526,627 has been canceled without prejudice and replaced.

~~PREBLEND OF MICROCRYSTALLINE CELLULOSE AND LACTASE FOR MAKING TABLETS~~

STABLE LACTASE TABLETS AND METHODS OF PRODUCTION

In the Abstract:

The abstract entered in Paper No. 14 of US Patent Application Ser. No. 09/526,627 has been canceled without prejudice and replaced.

~~A preblend for making lactase tablets is prepared containing about 1-99% (preferably about 20-60%) by weight lactase and about 1-99% (preferably about 40-80%) by weight microcrystalline cellulose. Lactase used in the preblend may be in combination with up to about 4 parts (preferably about 0.5-2 parts) by weight cutting agent such as sugars, starches, cellulose, and inorganic salts for each part by weight lactase. About 0.5-4% by weight lubricant such as magnesium stearate may be present in the preblend. A preferred preblend contains about 9.6 weight percent lactase and about 90 weight percent microcrystalline cellulose. Another preferred preblend contains about 9.6 weight percent lactase, about 30.0 weight percent microcrystalline cellulose and about 59.4 weight percent mannitol. Each preblend may also contain magnesium stearate. A preferred lactase is from Aspergillus oryzae and the microcrystalline cellulose preferably has an average particle size of about 20-200μm.~~

A tablet and a composition having from about 3000 to about 9000 FCC lactase units and from about 25 to about 70 weight percent microcrystalline cellulose is disclosed. Additionally, also disclosed is a process for making a tablet by following steps in order mixing lactase and microcrystalline cellulose to form a preblend; adding to the preblend a member selected from the group consisting of dextrose, mannitol, a lubricant, cornstarch, calcium phosphate, sodium citrate, calcium sulfate, calcium stearate, stearic acid, gylceryl monostearate, glyceryl distearate, sorbitol, gelatin, a gum, and mixtures thereof to form a mixture; and compressing the mixture to form a tablet.

In the Specification:

The following statement was entered at page 1, before the first line:

This application is a division of US Patent Application Ser. No. 09/526,627, filed August 16, 2000, currently pending, which was a division of US Patent Application Ser. ~~application Serial~~ No. 08/496,824, filed June 29, 1995, now US Patent No. 6,057,139.

In the Claims:

Claims 7-17 were canceled, without prejudice.

Claims 8-60 were added.